

Transition to EU IVD Regulation (EU) 2017/746 and considerations for non-EU regulatory authorities on managing the impact to product registrations



MAY 2022

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Transition to EU IVD Regulation (EU) 2017/746 and considerations for non-EU regulatory authorities on managing the impact to product registrations

Executive summary

More than 31,000 *in vitro* diagnostic medical devices (IVDs)¹ are expected to transition to the European Union's (EU) *in vitro* diagnostic medical devices Regulation (IVDR) 2017/746 within the next years. Non-EU regulators will see changes to these devices' regulatory documentation and labelling arising from the transition to EU IVDR. Because so many of these devices are transitioning around the same time, it is important for non-EU regulators to consider how to minimise disruption to the supply of IVDs in their country:

- In most cases, changes to regulatory documentation and labelling do not impact on the device's safety and performance – it will be the same IVD medical test with updated information.
- A pragmatic approach may be needed for handling e.g., change notification applications or other national regulatory requirements.

This document identifies considerations that can be shared with non-EU regulators on the recommended approach for handling changes deriving from the transition to the new EU regulatory framework. It builds on the experience gained so far with the transition as well as on a previous [MedTech Europe's publication](#) which informed about the nature of the changes and their relevance for international registrations².

Background

The European CE-marking system for IVDs has been revised and Europe is transitioning to the regulatory framework laid down by EU IVDR which will replace the IVD Directive 98/79/EC. The EU IVDR adopts a new classification system aligned with internationally agreed principles, brings the majority of IVDs³ under notified body review, and in general puts a heavier burden on safety and performance of the device to be demonstrated and documented, particularly by means of strengthened clinical evidence requirements. As a result, changes to IVD's regulatory documentation and labelling can be expected. At the same time, it is important to note that not all changes will apply to all IVDs and therefore changes to regulatory documentation and labelling due to EU IVDR are likely to vary from product to product.

¹ MedTech Europe coordinated survey for CAMD on IVDR, July 2021

² MedTech Europe, *Impact of changes under the new EU IVD Regulation (EU) 2017/746 to international registrations*, 26 May 2020.

³ MedTech Europe-coordinated [survey](#) for CAMD on IVDR, July 2021: There is a 736% increase in IVDs needing a certificate under IVDR compared with the IVDD. Under IVDD, 92% of IVDs do not need to have a certificate from a Notified Body. Certificates are only required for 8% of IVDs listed in Annex II or which are intended for self-testing. As a result of IVDR, 78% of devices will need a new certificate (including those needing to renew existing certificates).

Update to the transitional provisions

Regulation (EU) 2022/112 of 25 January 2022 amended the EU IVDR in regards to the transitional provisions for most IVDs. This was largely due to the unprecedented magnitude of the challenges linked with the situation imposed by the COVID-19 pandemic, the currently limited capacity of notified bodies and the overall lack of sufficient readiness of the regulatory system in order to effectively implement the EU IVDR among other challenges⁴.

The amendment extends the transitional provisions to allow most IVDs with their EC Declaration of Conformity under Directive (EC) 98/79 ('IVDD') to be placed on the market and or put into service for additional time depending on their appropriate risk class under the EU IVDR⁵. A sell-off provision is provided for IVDs which have already entered the supply chain before the end of their transitional period.

In summary, the most relevant considerations in the context of international registrations are (also see the visual below):

- **The 26 May 2022 date of application of the EU IVD Regulation remains unchanged, and:**
- Devices which are **Class A non-sterile** – including instruments, buffers, accessories without critical characteristics, general culture media etc. – must have CE-marking under the EU IVDR from the date of application in order to be placed on the market.

BUT, from the date of application:

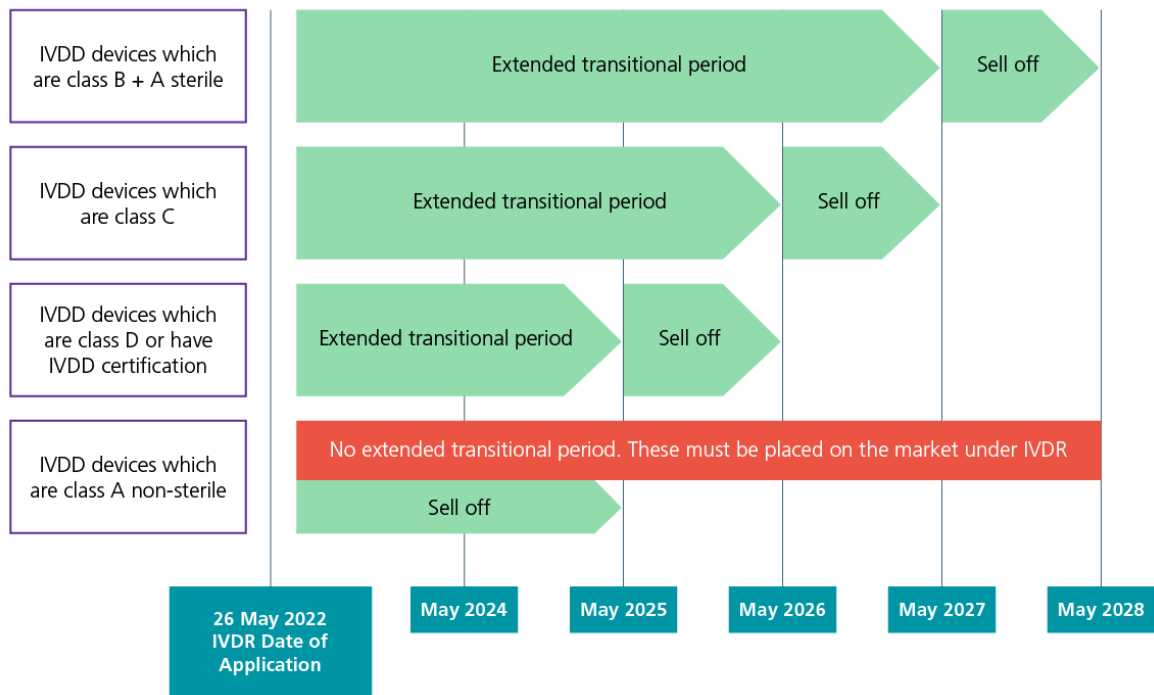
- EU IVDD devices which are **EU IVDR class D** or devices which have still-valid EU IVDD Notified Body certification – for example tests for blood safety, high risk infectious diseases (e.g., tests for COVID-19) – may be placed on the market or put into service until 26 May 2025. IVDs which are already placed on the market before that date may continue to be made available or put into service until 26 May 2026 (sell-off period).
- EU IVDD devices which are **EU IVDR class C** – for example cancer markers, tests for detection of dangerous infectious diseases (e.g., tests for detection of Syphilis) – may be placed on the market or put into service until 26 May 2026, a sell off period is provided until 26 May 2027.
- EU IVDD devices which are **EU IVDR class B or class A sterile** – for example blood chemistry, pregnancy tests or sterile blood tubes– may be placed on the market or put into service until 26 May 2027, a sell off period is provided until 26 May 2028.

⁴ Regulation (EU) 2022/112 of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and the deferred application of conditions for in-house devices [2022] OJ L 19/3

⁵ The transitional provisions under Article 110.3 ('extended transitional periods') and Article 110.4 ('sell-off') are extended to all devices that need Notified Body review under the EU IVDR and have their EU IVDD EC Declaration of Conformity drawn up before the EU IVDR date of application. More time also is given under the transitional period for devices with valid EU IVDD certification. Devices under the transitional periods cannot have significant changes to their design and intended purpose and they must also comply with certain EU IVDR requirements relating to market surveillance, post-market surveillance, vigilance, registration of economic operators and registration of devices (including under EUDAMED).

- EU IVDD devices which are placed on the market before the date of application ('old devices') may continue to be made available or put into service until 26 May 2025.

Amended transitional provisions For EU IVD Directive devices



CE-marking and its relevance beyond Europe

The concept of CE-marking is well established in the European Union (EU) law. CE-marking is used to indicate that the product conforms to all applicable EU legislation. It is a prerequisite for placing IVDs on the EU market and it is also used in various ways in many countries outside Europe, including e.g.:

- As a **registration requirement** to demonstrate approval in the country of origin/country of regulatory reference.
- As supplementary or mandatory part of the registration process – **Product labels and/or instructions for use** are submitted to support or required under local registration.
- As **part of the local submission to provide supporting information** for e.g., market approval history.
- As a **customer requirement in tenders**.
- In **product promotion** materials.

While manufacturers transition their devices to the new regulatory framework in Europe, it is relevant that they consider how changes to regulatory documentation are going to impact their international registrations and which actions would be triggered as a result. The impact will vary from company to company and from product to product.

Summary of the main changes arising from EU IVDR relevant for international registrations

EU IVDR lays down new requirements which in most cases make additional information about the product available. The Regulation adopts new classification system which will determine the applicable conformity assessment pathway which for most products entails involvement of a notified body. EU IVDR requirements will trigger changes – where applicable – to the product's regulatory documentation in the following areas:

- **Labels** – includes the addition of unique device identification (UDI), notified body number added to the CE mark, reference to a website where electronic instructions for use can be found and use of new symbols for near patient tests and self-tests.
- **Instructions for use (IFU)** – e.g., changes might concern the description of the intended purpose to fit the clinical evidence and the intended user. In some cases, IFUs might include additional information on clarification of performance data.
- **Certificates issued by a notified body** – IVDs that are subject to notified body oversight will require new notified body certificates. This affects 78% of IVDs (previously under the IVDD, only 8% of IVDs needed a notified body certificate). Complex transition periods mean that certain IVDs CE marked under the IVDD, may continue being sold until May 2025, May 2026 or May 2027 (depending on their risk class).
- **EU Declaration of conformity (EU DoC)** – new EU DoCs will be issued to claim conformity with EU IVDR. New DoCs will contain information including UDI, risk class of the device according to EU IVDR etc. (EU IVDR adopts a new classification system which is more closely aligned with international principles).
- **Certificates of free sale (CFS)** – EU IVDR repeals the IVD Directive (IVDD), therefore new CFS will be issued. Complex transition period means that certain IVDs which have CE-marking under the IVDD, may continue being sold until 2025. During this time, different CFS formats and reference either to IVDD or IVDR are likely to be issued.
- **Classification** – EU IVDR adopts new classification system which will determine the applicable conformity assessment pathway and e.g., IVDs classed under the EU IVDD under Annex II List A or Annex II List B will have a new NB certificate to reflect the requirements under the Regulation.

Ultimately, manufacturers need to assess the effect that changes arising from the transition to the EU IVDR will have to the safety and performance of their device, as they would in case of any other change during the device's life cycle. However, changes deriving from the transition to EU IVDR, are generally not expected to affect the use, effectiveness, performance or safety profile of the product. They also do not imply changes to the composition of ingredients or the manufacturing process, unless otherwise indicated.

Transition to the new regulatory framework may lead to other changes next to the ones driven by the legal requirements. To give an example, some manufacturers may issue new catalogue numbers for inventory management purposes and not by quality, performance or safety issues, as they transition into compliance with the new Regulation. It would be important to note that changes to product catalogue numbers, even though they are not driven by the requirements of the EU IVDR, they may be expected as a result of the transition to EU IVDR.

Expected impact of changes arising from EU IVDR and considerations for non-EU regulatory authorities

The impact of changes due to the transition to the EU IVDR is likely to vary across jurisdictions depending on the local requirements for reporting changes to registered products.

In general, changes that do not affect safety and/or performance of the device are considered as ‘**non-significant**’ or ‘**minor**’ changes, whereas changes that could reasonably be expected to affect the safety and/or performance of a device are considered as ‘**significant**’⁶. The terminology used to describe non-significant/significant change might differ among regulators however, the principle of categorising changes based on whether they impact safety and/or performance of the device is valid.

As already highlighted, changes to regulatory documentation due to the transition to EU IVDR are driven by the new legal requirements. Manufacturers need to assess the effect of these changes on case-by-case basis. As such, changes arising from the transition to EU IVDR that are not expected to influence safety and/or performance of the device, should be considered as non-significant.

One area where the effect of changes might require careful analysis pertains to changes to the intended purpose description in the IFU, which can be expected to be amended for certain IVDs. In general, changes to the intended purpose that arise from the device’s safety and/or performance concerns would be considered as ‘significant’. However, in case of changes due to transition to EU IVDR, it is important to understand that amendment to the intended purpose derives from the clinical evidence requirements that are laid down by the EU IVDR and not due to the device’s safety and/or performance concerns. Depending on the type of information available to support the claim, intended purpose description might need to be amended for certain products. This type of change needs to be assessed on case-by-case basis by the manufacturers so that it is categorised and notified appropriately according to the local requirements. AHWP/WG2-WG1-WG3/F001:2019 document ‘*Categorisation of Changes to a Registered Medical Device*’ (November 2019) indicates that labelling change which involves a reduction of intended use/indication of use not arising due to medical device safety and/or performance concerns, are non-significant, even though generally reportable⁷. Similarly, MDCG 2022-6 - *Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR* (May 2022), notes that not all changes concerning the design or intended purpose would automatically be regarded as ‘significant’, clarifying that e.g., limitation of the intended

⁶ AHWP, <http://www.ahwp.info/sites/default/files/01%20AHWP-WG2-WG1-WG3-F001-2019.pdf> (Retrieved: 09 November 2021)

⁷ AHWP/WG2-WG1-WG3/F001:2019, p. 26.

purpose, such as restricting the target population, specimen type, specimen location, would not be considered as ‘significant’⁸.

The requirements for reporting changes also vary among regulators. In some countries, all changes are reportable. Considering the nature of changes deriving from the transition to EU IVDR and the volume of notifications that can realistically be expected as devices transition into the new regulatory framework in Europe, regulators should consider a pragmatic approach for reporting changes to avoid any unintended disruptions to devices’ supply.

The extent to which CE-marking is used to support the local registration will also play a role in determining the impact of changes. Even regulators who do not rely on CE-marking to support registrations in their territory, can expect change notification applications, depending on what triggers change notification under the national requirements and the extent to which manufacturers use their CE labels/IFUs in domestic applications for product approval.

Regulators should therefore consider a pragmatic approach for handling applications arising from the new EU Regulation. E.g., **guidance** simplifying change notification requirements for changes deriving from the transition to the new European framework is worth considering for handling a significant volume of notifications. **Such guidance could be temporary in its application** i.e., applicable until the full transition to the EU IVDR has been accomplished (27 May 2027). It would provide much needed clarity and help in making the process smooth, limiting the administrative burden, and avoiding supply disruptions. Some regulators, e.g., Health Sciences Authority (HSA) in Singapore⁹ have already adopted such guidance.

The following sections contain input for regulators to consider when approaching changes arising from the transition to the new European IVD Regulation:

General considerations

Considering the volume of IVDs with CE-marking based on the IVDD that will move to the EU IVDR during the same time frame, regulators can expect a large volume of applications notifying changes arising due to the transition to the new Regulation. A pragmatic approach for management of these changes is urgently needed to ensure no disruption of supply to healthcare systems in non-EU countries.

Given the nature of changes deriving from the EU IVDR (in majority of cases, non-significant), consideration of the following aspects would help minimise the risk of disruptions to product’s supply as well as the administrative burden of the process, both for the regulator and for the applicant:

⁸ Medical Device Coordination Group, MDCG 2022-6 - Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR, May 2022 https://ec.europa.eu/health/latest-updates/mdcg-2022-6-guidance-significant-changes-regarding-transitional-provision-under-article-1103-ivdr-2022-05-04_en p. 7.

⁹ [https://www.hsa.gov.sg/docs/default-source/hprg-mdb/change-notifications-arising-from-the-eu-mdrivdr-related-changes-\(oct--pub\).pdf](https://www.hsa.gov.sg/docs/default-source/hprg-mdb/change-notifications-arising-from-the-eu-mdrivdr-related-changes-(oct--pub).pdf) (Retrieved: 09 November 2021)

- Allowing notification of multiple changes for one product in a single submission¹⁰
- Notification of changes affecting multiple registered IVDs in one submission, e.g., within 6 months from the first implementation¹¹
- No limit to the number of listings in one change notification submission if the changes are the same¹²
- Enabling immediate implementation of changes without the need to await approval of the notification
- For jurisdictions that require approval of changes prior to their implementation:
 - A fast-track review for changes arising from the implementation of the EU IVDR. In such cases, regulators can consider reliance through recognition of references to approvals by other jurisdiction e.g.: *'If the manufacturer can provide proof that the proposed change has been assessed and accepted by another jurisdiction, the regulatory authority may make an informed decision of acceptance or rejection of the change based on abbreviated review or waive the review.'*¹³
 - Agreeing with the manufacturer a transition timeframe for approval of labelling changes (e.g., packaging and package inserts)
- Allowing the coexistence of products certified under EU IVDD and EU IVDR on the market for certain time (i.e., during the extended transition periods)
- Coordination with customs authorities to prevent potential issues at the point of importation

Changes to Labels

IVDR requirements will trigger label updates. As a result, the label layout might need to be updated. The information displayed on the label might be rearranged to accommodate the new legal requirements on the label, including e.g.:

- Notified body number next to CE-marking – this will be a change for many IVDs that have not been subject to notified body oversight under the EU IVDD
- Unique device identification (UDI), in the form of a barcode accompanied by human readable text
- Addition of symbols for near patient tests and self-tests
- Addition of a hyperlink adjacent to 'consult IFU' symbol and/or reference to 'electronic IFU'

A visual example below:

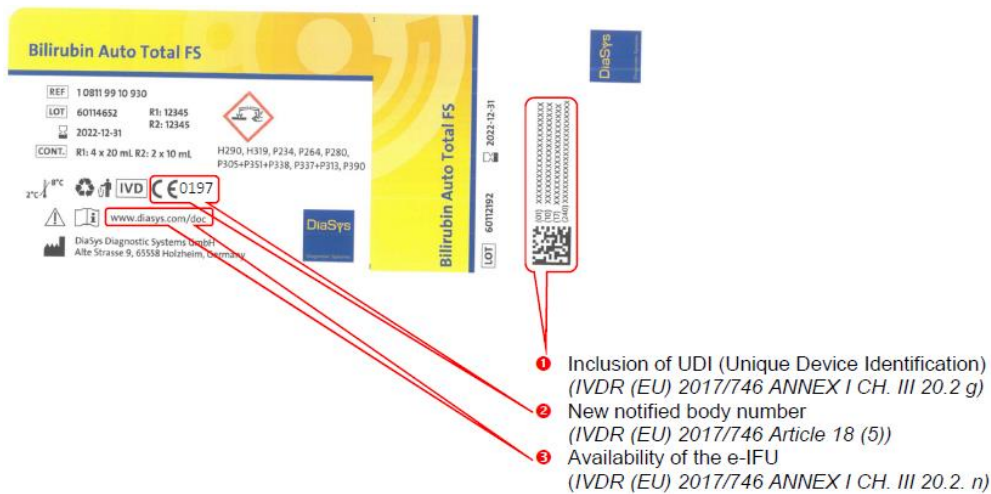
¹⁰ <http://www.ahwp.info/sites/default/files/01%20AHWP-WG2-WG1-WG3-F001-2019.pdf> p. 27.

¹¹ Supported by HSA guidance: [https://www.hsa.gov.sg/docs/default-source/hprg-mdb/change-notifications-arising-from-the-eu-mdrivdr-related-changes-\(oct---pub\).pdf](https://www.hsa.gov.sg/docs/default-source/hprg-mdb/change-notifications-arising-from-the-eu-mdrivdr-related-changes-(oct---pub).pdf) p. 9, 11.

¹² Supported by HSA guidance: [https://www.hsa.gov.sg/docs/default-source/hprg-mdb/change-notifications-arising-from-the-eu-mdrivdr-related-changes-\(oct---pub\).pdf](https://www.hsa.gov.sg/docs/default-source/hprg-mdb/change-notifications-arising-from-the-eu-mdrivdr-related-changes-(oct---pub).pdf) p. 9.

¹³ <http://www.ahwp.info/sites/default/files/01%20AHWP-WG2-WG1-WG3-F001-2019.pdf> p. 27.

Kit label under *in vitro* diagnostic medical devices Regulation (EU) 2017/746



The table below displays examples and a suggested approach for management of changes to labels:

Example	Suggested category	Change notification submission
Changes to label with no new information related to safety and/or performance e.g., addition of symbols, UDI, etc.	Non-significant	Not required ¹⁴
Change that involves a reduction of intended purpose not arising due to medical device safety and/or performance concerns	Non-significant	Generally reportable ¹⁵

¹⁴ Reference: HSA guidance (6 October 2020) p. 4-5; AHWP/WG2-WG1-WG3/F001:2019 (November 2019), p. 26.

¹⁵ Reference: AHWP/WG2-WG1-WG3/F001:2019 (November 2019), p. 26.

Changes to Instructions For Use (IFU)

The table below displays examples and a suggested approach for management of changes to IFU:

Example	Suggested category	Change notification submission
<p>Changes to IFU with no new information related to safety and/or performance</p> <p>e.g., Addition of a link to EUDAMED, warnings and precautions related to safe disposal of the device, addition of a statement to report serious safety incident to EU manufacturer and Member State competent authority etc.</p>	Non-significant	Not required ¹⁶
<p>Change to IFU related to clarification of existing content and addition of safety information</p> <p>e.g., Minor update of intended purpose with no change to approved scope (rephrasing intended purpose for clarity, based on existing clinical studies)</p>	Non-significant	Notification ¹⁷
<p>Changes to IFU related to clarification of performance data</p> <p>e.g., Addition or clarification of performance data, based on previously submitted pre-clinical or clinical studies, where the key parameters (analytes measured, reportable range, etc.) are not changed, and additional (or more recent) performance data are included to further substantiate previously established/approved performance claims.</p>	Non-significant	Notification ¹⁸
<p>Change that involves a reduction of intended purpose not arising due to medical device safety and/or performance concerns.</p>	Non-significant	Generally reportable ¹⁹

¹⁶ Reference: HSA guidance (6 October 2020) p. 4-5; AHWP/WG2-WG1-WG3/F001:2019 (November 2019), p. 26.

¹⁷ Reference: HSA guidance (6 October 2020) p. 7.

¹⁸ Reference: HSA guidance (6 October 2020) p. 7.

¹⁹ Reference: AHWP/WG2-WG1-WG3/F001:2019 (November 2019), p. 26.

Changes to notified body certificates, declaration of conformity and classification

CE certificates issued by EU notified bodies and Declaration of Conformity (DoC) are often submitted to support registrations to access the markets in many jurisdictions outside Europe. It is understood that manufacturers need to maintain continuity of such certification to ensure continued supply of devices.

For IVDs, under the EU IVDD, notified body certificates are issued for 8% of devices (those falling under Annex II List A, Annex II List B or which are self-tests). However, under the EU IVDR, notified body certification is needed for 78% of IVDs (since they are classified under class B, C, D, and sterile class A). It is important to note that the certificate issued by a notified body under the EU IVDD will remain valid after the date of application of the EU IVDR until the end of its validity, or until 27 May 2025 (whichever is earlier).

The transitional arrangements under the EU IVDR are challenging as currently, the number of notified bodies designated under the new Regulation is very limited: 53% of the IVD sector reports that they have no contract with a notified body to certify their devices ahead of the date of application (27 May 2022). Once this obstacle is cleared and manufacturers are able to find a notified body to carry out conformity assessment for their products, new notified body certificates will be issued.

Regulators can expect to see notified body certificates issued under a new format, including additional information such as e.g., Basic UDI, expanded scope based on the classification under the EU IVDR, *etc.*

Changes to notified body certificates and the Declaration of Conformity, do not affect safety and performance of the device, therefore as such should be considered as non-significant changes.

Changes to classification of IVDs, which changes fundamentally under the EU IVDR, will determine the applicable conformity assessment requirements and as such, does not imply changes to the product's safety and/or performance and should also be considered as non-significant. For countries that have their own classification system, changes due to the EU IVDR in this area should not be relevant.

The table below displays examples and a suggested approach for management of changes to notified body certificate, DoC and classification:

Example	Suggested category	Change notification submission
Changes to notified body certificate e.g., certificate issued under the EU IVDR rather than EU IVDD.	Non-significant	Not required
Changes to Declaration of Conformity (DoC) e.g., DoC claiming conformity to EU IVDR, addition of Basic UDI or where applicable references to common specifications or harmonised standards, single registration number of the manufacturer and EU authorised representative, new layout etc.	Non-significant	Notification
Changes to product's classification to reflect EU IVDR requirements. All IVDs will receive a new classification under A, B, C or D.	Non-significant	Not required

Transitional measures and Class A IVDs

According to the transitional measures included in the EU IVDR (Article 110), IVDs placed on the market pursuant to IVDD (Directive 98/79/EC) prior to 26 May 2022 may continue to be made available on the market or put into service until the end of the applicable transitional provisions.

This means that it will be possible to have in the market at the same time (and up to three to six years), products certified under the IVDD, and products already certified under the EU IVDR. It is normal and permitted under the EU IVDR for these products to co-exist under different regimes.

This means it will be normal for many instruments to be on the market under the EU IVDR while their reagents are under the IVDD, until the applicable transitional provisions end. This will not impact the performance, the intended use, and the characteristics of the system, unless there are significant changes introduced by the manufacturer in the system itself.

The instruments should already go through the relevant regulatory approval or clearance once they come under the EU IVDR for its May 2022 deadline. The related reagents will be transitioned to the EU IVDR only after the instruments according to the transitional provisions – their EU IVDR certification should not impact the regulatory approval status or clearance of the related instruments in any non-EU country.

Example	Suggested category	Change notification submission
Changes to notified body certificate e.g., certificate issued under the EU IVDR rather than EU IVDD.	Non-significant	Not required

Changes to certificates of free sale

Certificates of free sale (CFS) are also used to support product registrations in many jurisdictions. CFS are used as proof that the products covered by the certificate circulate freely on the market, and that the applicant has demonstrated that the products meet the applicable legislative requirements. CFS is therefore often treated as evidence of regulatory approval in the jurisdiction of reference.

As Europe moves to the new regulatory framework, due to the complex transitional arrangements, when devices certified under IVDD and EU IVDR will co-exist on the market for certain time (up to three to six years), regulators outside Europe can expect to see CFS issued either under the IVDD or under the EU IVDR. It will be important that this is recognised and that both are considered equally valid²⁰.

²⁰ <https://ec.europa.eu/docsroom/documents/33863> p. 3.

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About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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